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Comparison of dexmedetomidine with fentanyl as intravenous adjuvants to propofol induction for LMA supreme insertion

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Abstract
Objectives: To compare the efficacy, safety, hemodynamic stability, of Laryngeal mask airway supreme insertion using Dexmedetomidine as an adjuvant to Propofol.
Method: The present double-blind, randomized, prospective study included sixty subjects in the age range 18-50 years of both sexes who are either Grade I / grade II undergoing elective surgery under general anesthesia. Random allocation into Groups A and B was done. Group A was administered with a 1µg/kg-loading dose of Dexmedetomidine over 10 minutes thereafter by infusion at dose of 0.7µg/Kg/Hr. Group B received a 1µg/kg-loading dose of fentanyl over 10 minutes, then infusion at dose of 0.7µg/Kg/Hr. After completion of the initial dose of either agent, propofol infusion was initiated at the dose of 100µg/kg/min titrated to keep BIS at 40-60 for Laryngeal mask airway supreme insertion. Hemodynamic parameters, BIS values, Insertion quality score, number of attempts, induction time, and doses of propofol are compared.
Results: In groups, A and B laryngeal mask airway supreme insertion was accomplished in the first attempt in 84% and 80% of subjects respectively. The insertion quality score was better in group A.
A significant difference in hemodynamic parameters and bisepctral index between the two groups from the end of infusion to 5 minutes after laryngeal mask airway unique insertion was noted. In group B 7(28%) reported sore throat postoperatively and 8 (32%) patients had pain on injection.
Conclusion: Dexmedetomidine propofol combination provides better insertion quality, lower propofol consumption, and hemodynamic stability than propofol alone.

Keywords: Dexmedetomidine, insertion quality, laryngeal mask airway, propofol

Introduction
Dr. Archie Brain devised supraglottic airway device (LMA) has revolutionized the anaesthetic procedures [1]. LMA insertion necessitates an optimum depth of anaesthesia to allow adequate relaxation of the jaw and prevention of reflexes of upper airway along with maintaining a cardio-respiratory equilibrium in a non-paralyzed patient [2]. Propofol as an induction agent for insertion of LMA has been widely used [2, 3]. For a quality LMA insertion use of propofol at 2.5 mg/Kg is practiced routinely but is accompanied with cardiovascular and respiratory depression [4].
Widely addressed alpha-2 agonist Dexmedetomidine (DMED) has sedative, analgesic, and sympatholytic effects. Patients receiving dexmedetomidine show minimal evidence of respiratory depression despite deep sedation, and are easily arousable by either tactile or verbal stimulation [5, 6]. Literature has shown that when dexmedetomidine is used perioperatively for maintaining BIS 40-50, the requirement of propofol for induction and maintenance were reduced significantly [7]. Dexmedetomidine is known to minimize airway reflexes and provide cardiovascular stability at intubation while carrying out extubation [8].
This study is primarily outlined to appreciate the differences the successful insertion of LMA when propofol induction was supplemented with dexmedetomidine or fentanyl infusion.

Material and Methods
This experimental, randomised study was carried out after procuring informed written consent from the subjects. The research was conducted in accordance to the principles for medical research on humans in agreement with the Helsinki Declaration, December 2013 The study was carried out in a teaching hospital.

Ninety patients in the age group 18-50years of both sexes and American Society Of Anaesthesiologists [ASA] grade I / grade II were studied over 12 months (1st March 2019 to 29th Feburary 2020) of either sex undergoing general anesthesia requiring supraglottic placement for an elective surgery were chosen as study subjects. Patients with a current respiratory disorder, severe hepatic, cardiac, renal, or significant neurologic disorders, smokers, patients undergoing oral surgery, airway abnormalities, and known allergies to any of the drugs were not included from the study.

Computer based and virtual random number allocation was done to assign the patients either groups A or B. Group A was administered a 1µg/kg- of dexmedetomidine (dexmedetomidine 2ml ampoule, Manufacturer - Xamdex, Abbott India Ltd, Mumbai) which is a loading dose given over ten minutes thereafter an infusion at 0.7µg/Kg/Hr. Group B received a 1µg/kg-loading dose of fentanyl (fentanyl 2ml ampoule, Manufacturer - Troika Pharmaceuticals Ltd, Gujarat, India) over ten minutes continued by infusion at 0.7 µg/Kg/Hr

Two ml of the study drug diluted with 48 ml of normal saline and started at the rate of 1µg/kg over 10 minutes by an independent anaesthesia technician who was not included further in the study. The test drug infusion was initiated by the attending anaesthesiologist who was blinded to the test drug after all monitors were in place drug using a syringe pump (Mindray bene infusion SP1 serial noSN10524653) and was not included further in the study.

After a detailed pre anaesthetic examination, patients were advised 10 hours of fasting before surgery. Tablet Alprazolam of dose 0.5 mg at night followed by. 25 mg before surgery with sips water was prescribed to all subjects. After with, pre-procedural checklist the IV access was established Ringer's lactate was started. Baseline readings of bispectral index (BIS), heart rate; Blood pressure (HR, SBP, DBP, MAP); SpO2; electrocardiograph (ECG) were noted with patient in supine position where head is rested over pillow of 7 cms height. Pe-oxygenation with 100% oxygen was for three minutes, followed by the initial dose of either agent, after which all patients received propofol infusion at the rate of 100 µg/kg/min titrated to keep BIS at 40-60 throughout the procedure. Laryngeal mask airway was inserted after attaining a BIS value of 60. All the maneuvers were performed by a single investigator with experience of more than >30 LMA insertions. The size of the LMA was chosen according to body weight. Prior to each insertion, the LMA was well lubricated as per manufacturing guidelines. With anaesthetist standing at the head end of the patient. And equipment placed next to patient's head on the operating table, given on the count of three, introducer was to pick the device and attempt at LMA introduction by standard technique. Stopwatch was used to time each attempt. The satisfactory placement of the device was confirmed by auscultations of breath sounds and equal air entry which ruled out the down folding of the epiglottis over the laryngeal opening, capnographic square wave and SpO2 > 95%. In absence of either of above findings, further attempts at insertion were carried out. Despite 3 consecutive trials if an effective airway was not maintained then it was deemed as a failed attempt. An experienced senior anaesthetist would introduce the LMA in failed attempts.

Heart rate, Blood pressure, Mean arterial pressure, SpO2, and ECG readings at insertion, and one, three and five minutes after insertion were recorded. Any kind of stimulus including the painting and draping by surgeon were avoided following insertion up to 5 min to minimize the interference with findings. The attempts at LMA insertion and Insertion Quality Score (IQS) as follows [2, 6] and was noted by an investigator who was not further involved in the study.

Score of 1: Complete mouth opening without any movement.

Score of 2: Partial mouth opening, minimal gagging, and movements of fingers.

Score of 3: Difficult mouth opening, gross limbs movement and coughing.

Any injury to lip or teeth and buccal mucosa, or sign of bleeding on the LMA were noted. Any episode of coughing, gagging, gross purposeful movement, breath-holding, laryngospasm, lacrimation, expiratory stridor, desaturation, and arrhythmia was recorded. Time from the beginning of Propofol infusion till end of LMA insertion was considered as induction time. The total dose of the propofol and study drugs used were noted. In case of any movement during and later the insertion propofol 0.5 mg/kg was topped up and after 30 sec next attempt was taken.

Maintenance of anaesthesia was with oxygen (66%), nitrous oxide (33%) and sevoflurane (1–2%). No muscle relaxant given. After the procedure, the infusion was stopped and100% oxygen was administered. After the commands (mouth opening) were followed by patients, oral suctioning was done and subsequently, the LMA was removed after patient could maintain adequate respiratory rate and depth.

Infusion rates of study agent were titrated by 0.1µug/kg/hr to according to MAP and HR to maintain ±30% from the baseline value. Bradycardia was defined as heart rate <60beats per minute and treated with iv atropine 0.02mg/kg

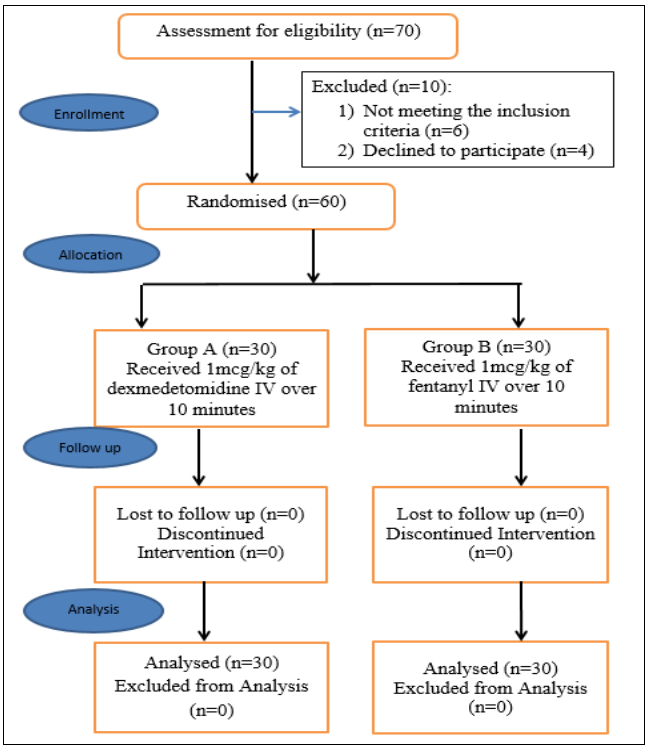

Fig 1: CONSORT (Consolidated Standards of Reporting Trials) diagram depicting the flow of study patients

Statistical analysis

Sintavanuruk K *et al*. reported mean BSI score was 51.4 in bolus injection and 58.4 in target control injection [2]. Our estimated sample size is based on the BIS score (post-LMA insertion) among groups. For the sample size calculation, we have defined a mean difference of 0.6 with 5 Standard Deviations. We have calculated sample size with a 95% confidence interval, 80% power, an alpha level of 0.05

The variables were assessed for normality with the Kolmogorov Smirnov test. statistics including computation of percentages, means, and standard deviations were done. Independent unpaired "t"-test was used for demographic data, time taken for induction, hemodynamic parameters, and BIS value. The Pearson's Chi-Square test was applied for of sexes, attempts taken to insert LMA, and insertion quality. A p-value <0.05 was taken as significant.

Results

Significant difference was not observed in demographic profile in both groups (Table 1). Apnoea time, quality of LMA insertion, any additional propofol requirement indicating the attempts at LMA insertion were different significantly in both groups and were summarized in Table 2. Hemodynamic parameters over the time intervals were shown in Table 3. significant difference in baseline heart rate variability was not found in both group from baseline to all the time intervals observed. At the end of infusion, we observed a significant difference in heart rate from baseline at all-time intervals. Only1 (3.3%) patient received atropine in Group B and was statistically insignificant. There was a transient, reduction in DBP, SBP, and MAP at the end of infusion and at T1, T3, T5 following induction which were clinically not significant, and did not require any medication.

Significant difference was noted in depth of anaesthesia from the completion of infusion of the study drugs to five minutes after insertion in two groups. Significantly lower BIS scores were seen in dexmedetomidine group compared to fentanyl group during post-LMA insertion period. 5(16.7%) subjects in the group had a cough at the time of insertion of LMA supreme as compared to Group A 2(6.67%) which was statistically significant. (Table 3). Incidence of hypotension or hypoxemia (SpO2 <90%) was not seen in the study.

Table 1: Demographic parameters

	Group A	Group B	p value
Age(years)	34.80±7.10	34.17±7.60	0.74
Gender (Male: Female)	20:10	14:16	0.11
Weight (kg)	61.43±10.82	63.47±9.80	0.44
ASA Grade I:II	29:1	30:0	0.31
LMA Size 3:4:5	14:11:5	10:14:6	0.57

Table 2: Comparison of induction parameters among groups

	Group A	Group B	p value
Total Propofol Dose (mg)	83±25.15	126.83±15.61	0.001*
Aponea time (sec)	115.77±29.05	130.30±38.04	0.1
Time Taken for insertion (sec)	22.20±4.16	27.57±10.70	0.01*
No. of attempts (1:2:3)	25:5	23:5:2	0.13
IQS Score 1:2:3	27:3	21:7:2	0.04*

Table 3: Comparison of complications among the groups

		Coughing	Gagging	Laryngospasms	Desaturation	Arrhythmia	Breath holding	Pain on inj	Sore throat	Bloodstained
Group A	%	6.7%	10.0%	0.0%	0.0%	0.0%	0.0%	10%	10.0%	13.3%
Group B	%	16.7%	20.0%	3.3%	3.3%	3.3%	6.7%	26.7%	16.7%	13.3%
TOTAL	%	11.7%	15.0%	1.7%	1.7%	1.7%	3.3%	18.3%	13.3%	13.3%
P value		0.01 (S)	0.31	0.3	0.3	0.3	0.15	0.18	0.44	--

Discussion

LMA is most commonly used in ambulatory surgery. LMA insertion mandates adequate suppression of airway reflexes. Till date, propofol is considered to be an ideal induction agent. Our study outlines the comparison of the usage of fentanyl with dexmedetomidine prior to administration of the induction agent propofol. Past research has showed that using propofol alone for induction is incomplete to repress the airway reflexes, and when administered as incremental doses along with fentanyl, a dose-related action is seen alongside posing a threat of muscle rigidity [10]. Studies have also compared inhalational induction with intravenous propofol induction, which have proved requirement of greater time for causing airway reflexes suppression. The more frequently stated success rate of the combination with opioid by various studies may be due to the, analgesic, and antitussive and apneic effects of the opioid. Dexmedetomidine which is an alpha -2 agonist was also studied to reduce the airway and cardio vascular responses to intubation and also provide smooth extubation. This is a novel study in which both the drugs were given as infusions. We did not include a third group i.e (propofol only) as previous studies have indicated that when used alone, propofol is far from ideal in providing satisfactory conditions for LMA insertion, causing hemodynamic depression. [9].

In our study, Group A had shorter mean duration of apnea as compared to group B though it was not clinically significant. Dexmedetomidine sedation is compared to natural sleep with minimal affliction of respiration and ventilation. Dexmedetomidine does not potentiate respiratory depression usually caused by propofol. [11]. We had one incidence of laryngospasm in group B our study which was relieved by giving gentle manual ventilation.

In our study, Extent of rise in SBP and MAP was more in Group A at insertion, immediately after insertion, while at 1,3,5 minutes after insertion group B had higher values.Our results differ from the result observed by Jayaram AS *et al*. who observed propofol combined with dexmedetomidine produces similar LMA insertion conditions as compared to combination of propofol with fentanyl, albeit with improved maintenance of haemodynamic parameters. The difference can be explained owing to the drug administration where induction was done with i.v. propofol 2 mg/ kg common to both groups after thirty seconds of the study drug (fentanyl 1 µg/kg in Group B and dexmedetomidine 1 µg/kg in Group A diluted in 10 mL normal saline over 2 min)administration,. LMA insertion was carried out after 90 seconds of propofol injection by assessing relaxation of jaw. Instead of bolus dosing, Dexmedetomidine in our study, given as infusion was advantageous as it is known to cause sympatholysis due to agonist action on central alpha -2 adrenergic receptors causing only slight variations in the heart rate [13] and provided a study state drug concentration. On the other hand, bolus doses of dexmedetomidine is not widely advocated owing to its fluctuating effects causing bradycardia and initial increase in blood pressure by causing vasoconstriction and increased peripheral vascular

resistance which is succeeded by decreased sympathetic outflow and mean arterial pressure. In majority of patients, time taken for LMA insertion is 20-30 seconds. In patients who received fentanyl, the time of insertion is prolonged compared to dexmedetomidine. Study by Lee *et al*. [14] on induction with 8% sevoflurane, premedication with with fentanyl at (1 mcg/kg) and propofol at (0.5 mg/kg) showed significant reduction in the time of LMA insertion in contrast to sevoflurane alone. Our study showed increased coughing in the fentanyl group compared to dexmedetomidine, which was not a significant finding of other studies. Another similar study done by Ramaswamy and Shaikh, which used Fentanyl and Dexmedetomidine both in a dose of 1 µg/kg over 2 minutes along with propofol and proved that both provided similar quality of LMA insertion when combined with propofol. But these studies did not apply BIS monitoring and were at a disadvantage as key factor, i.e level of awareness during a LMA insertion was unknown. BIS monitoring was used in our study to assess the level of sedation. Glass *et al*. reported that BIS scoring is superior to propofol plasma concentration in assessing the correlation of response to stimuli BIS scoring system with grades from 0-100 calculated from clinical data and electroencephalographic spectral analysis. BIS scores approximately 40-60 indicates appropriate sedative and hypnotic state. Our study provided results stating that mean BIS value at the end for infusion was low in group A compared to group B with a significance especially in post insertion period. These factors collectively could have been responsible for the difference in results. In our study infusion of study drugs provided a sustained concentration and use of BIS enabled to assess the depth before insertion [12].

Limitations
All the patients belonged to ASA grade I, II with normal airways. More studies should be conducted regarding the correct dose of dexmedetomidine for patients with unstable hemodynamics or difficult airway.

Conclusion
This study suggests that 1µg/kg dexmedetomidine adjuvant to propofol provided superior LMA insertion conditions than 1µg/kg fentanyl with propofol without neuromuscular blockade

Conflict of Interest
Not available

Financial Support
Not available

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